

REMARKS

Reconsideration of this application is requested.

The pending claims are prior claims 1, 2, 4-27 and new claims 28-31.

Claim 1 has been amended to include the feature of claim 3 and to otherwise improve the definition of the applicants' invention.

Claims 10, 11 and 24 have been amended to obviate the objections thereto as set out on page 2, 2nd full ¶ of the action.

Claim 15 has been amended in a way which is thought to remove the basis for the Examiner's Section 112, 1st ¶ rejection thereof (last ¶, page 2 and ¶ bridging pages 2-3 of the action). Reconsideration of this rejection of claims 15-17 with its withdrawal is requested.

The claims have also been amended to obviate the Examiner's Section 112, 2nd ¶ rejection as set out on pages 3-4 of the action. The manner in which the Examiner's objections have been dealt with is thought to be self-evident so that detailed comment thereon is believed to be unnecessary. The Examiner is requested to reconsider and withdraw this rejection.

New claim 28 has been presented in order to cover the applicants' method. Support for the claim is found throughout the disclosure, particularly at page 5, 4th ¶.

New claims 29, 30 and 31 are drawn to preferred features previously recited in claims 11, 11 and 23, respectively.

The Examiner is respectfully requested to reconsider (1) the Section 102(b) rejection of claims 1-4, 6, 7, 12, 22 and 26 as anticipated by Powell (U.S. 4,327,731) and (2) the Section 102(b) rejection of claims 1-9, 11, 18, 19 and 21 as anticipated by Green (WO 01/28600). While the Examiner has made separate Section 102(b) rejections based on Powell and Green, it is thought to be appropriate to consider both rejections together, particularly since there is an overlap in the rejected claims and applicants' main claim (claim 1) is included in both rejections.

The applicants respectfully submit that the Green and Powell references do not disclose the applicants' invention as defined by the rejected claims.

The present invention concerns a layered dressing that includes a supply of water (in the second dressing component) for hydration of dried enzyme (in the first dressing component), enabling rapid, controlled and predictable hydration of the enzyme in use to produce hydrogen peroxide (see page 6 of applicants' specification). This results in transport of oxygen from the ambient atmosphere to the skin surface (see applicants' disclosure at pages 16 and 17) with benefits for

wound healing, and also optional delivery of iodine if iodide is present (pages 8 to 9 of applicants' disclosure). A crucial feature is the inclusion in the dressing (prior to use) of a source of water.

Powell and Green are fundamentally different from the applicants' invention as defined in, for example, main claim 1. More specifically, Powell discloses a moisture indicator that may be used in a surgical dressing (abstract line 3). The moisture indicator is of layered construction and may include glucose oxidase, peroxidase enzyme and potassium iodide (Col. 2, lines 54 to 63), resulting in a visible color change when an absorbent layer 11 has absorbed sufficient moisture (Figure 1). The Examiner considers layer 11 and/or layer 14 when moistened in use to be equivalent to the second dressing component carrying a source of water as called for in applicants' claims.

Green (of Oxybio) is acknowledged in the applicants' specification on page 4. This reference concerns the generation of iodine from an initially dry structure, possibly of layered configuration (as in Figure 2). The dressing is wetted in use, either by body fluid or by water introduced to the dressing during its application (page 14, line 8). The specification mainly concerns monolayer dressings, and includes only a short discussion of bilayer dressings (mainly on pages 12-14), and has no examples of bilayer dressing embodiments. The layered dressing of Figure 2 has a lower layer 22 including a proton source which may be oxidoreductase enzyme (page 9, line 5), and an upper layer 21 including iodide. In use, upper layer 21 becomes wetted, and the Examiner equates the wetted dressing layer 21 to applicants' second dressing component carrying a source of water.

Neither Powell nor Green discloses a dressing initially supplied with water, as with the present invention. The second dressing component of applicants' dressing carries a source of water prior to use. This is fundamentally different from what Green and Powell disclose. In fact, the functioning of the Powell structure would be undermined entirely if water were present initially, given that the aim is to act as a moisture indicator. It would thus be completely inappropriate to pre-wet layer 11 of Figure 1 of Powell.

With respect to Green, it is noted that in use of the Green dressing, there is no stage in which the enzyme-containing (lower) layer 22 is dry while the upper layer 21 is wet. The dressing is initially dry. Water from wound fluid initially wets the lower, enzyme-containing layer. By the time the upper layer is wet, with water from the permeated wound fluid and possibly also water generated in the reaction of equation 1 on page 8 of Green, the enzyme-containing layer is also wet. Thus, at no

stage in Green is there found the applicants' combination of a dry enzyme-containing layer and a second water-containing layer, as in the present claims.

It is noted, in addition, that the Green dressing does not include a source of substrate for the enzyme. The dressing instead relies on use of glucose in wound fluid, for instance as specified in claims 4 to 6; page 6, paragraph 1; page 9, paragraph 2; and page 20, paragraph 2. Applicants' claim 1, as amended, calls for the presence of a source of substrate for the enzyme in the dressing (prior claim 3). This may either be in the second dressing component or in a separate dressing component, as explained on page 8, paragraph 1 of the applicants' specification. Green is silent as to this feature of claim 1.

A further distinction between the applicants' invention and Green's disclosure is that the two component arrangement in Green is used in the reverse orientation to the dressing of the present invention. Thus, in Green, the "proton donating" enzyme layer 22 is used adjacent to the skin (page 13, lines 30 to 31) whereas in the present invention the enzyme is kept away from the skin (page 3 paragraph 4). This orientation is critical for the oxygen transport function of the dressing of the present invention, which does not occur in the Green prior art dressings. This distinction is also brought out in applicants' claim 1.

For the reasons indicated, the applicants respectfully submit that their claims define subject matter which is not anticipated by Powell or Green. Accordingly, reconsideration and withdrawal of the Section 102(b) rejections is requested.

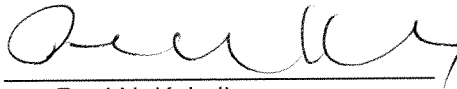
The Examiner is also requested to reconsider the Section 103(a) rejection of claims 1-27 as unpatentable over Powell in view of Green, Munro (U.S. 2002/0037270) and Fuchs (U.S. 5,483,697). The applicants' invention is not obvious from the Examiner's reference combination. The same is true with respect to the Examiner's combination of Green with Munro and Fuchs. Accordingly, reconsideration and withdrawal of both of the Examiner's Section 103(a) rejections as set out on pages 8-13 of the action is requested.

Briefly stated, the applicants consider their invention as defined by all of the claims herein, including new claims 28-31, to be unobvious from the references which the Examiner has combined to reject original claims 1-27. The deficiencies of Green and Powell have been noted above. Fuchs and Munro do not fill in the fundamental deficiencies of Green and/or Powell which have been noted. Munro discloses hydrogel wound dressings, e.g. of polyAMPS, but not including oxidoreductase enzymes while Fuchs discloses layered protective coverings such as surgical gloves made of hydrogels. Neither Munro nor Fuchs supply any teaching of

the critical features of the applicants' invention as set out above in differentiating the invention from Powell and Green. Clearly, in the circumstances, the Examiner's Section 103(a) rejections should be withdrawn and such action is requested.

The applicants submit that the application is in allowable condition.
Accordingly, favorable reconsideration with allowance is requested.

Respectfully submitted,
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